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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/672,375	09/25/2003	Cang Lam	31150-1170 (USGI-005 CIP	8551

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EXAMINER	
WOO, JULIAN W	
ART UNIT	**PAPER NUMBER**
3731	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/27/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

HH

Office Action Summary	Application No.	Applicant(s)	
	10/672,375	LAM ET AL.	
	Examiner	Art Unit	
	Julian W. Woo	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 February 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15 and 17-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15 and 17-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Kensey et al. (5,545,178). Kensey et al. disclose, at least in figures 3-5, 15, 16, 24, and 25; an apparatus for securing a tissue fold within a patient, where the apparatus includes a plication apparatus adapted to from a tissue fold within a patient (104, e.g., as seen in fig. 15), an anchor assembly (e.g., 200) having proximal (202) and distal (106) anchors connected by a suture (108), where the anchor assembly is adapted for adjustment of the length of suture between the anchors (e.g., as seen in figs. 23-25), where the anchor assembly is adapted for unidirectional and bi-directional adjustments of the length of suture, where the proximal anchor is adapted for adjustment of the length of suture between the proximal and distal anchors, where the proximal anchor comprises an adjustment mechanism (102 along with 108B and 108C as seen in fig. 23), where the distal anchor is substantially fixed with respect to the suture; where the adjustment mechanism comprises a one-way valve (e.g., 102D), a slipknot (108G as seen in fig.

25) formed near the distal end of the suture, and an inclined plane (on 202 when it is inclined relative to the longitudinal axis of 102); and where the apparatus includes an anchor delivery system (102). Note: The introductory statement of intended use ("for securing a tissue fold within a patient") has been carefully considered but deemed not to impose any structural limitations on the claims patentably distinguishable over the device of Kensey et al., which is capable of being used as claimed if one desires to do so. Also, it has been held that the recitation that an element is "adapted to" or "adapted for" (e.g., "adapted to form a tissue fold within a patient" and "adapted for adjustment of the length of suture") is not a positive limitation, but only requires the ability to so perform. It does not necessarily constitute a limitation in a patentable sense.

3. Claims 1 and 8 are rejected under 35 U.S.C. 102(e) as being anticipated by Swanstrom et al. (6,669,707). Swanstrom et al. disclose, at least in figures 10 and 22, 28-30 and in col. 15, line 39 to col. 16, line 11; an apparatus for securing a tissue fold within a patient, where the apparatus includes a plication apparatus adapted to from a tissue fold within a patient (T, T1, or T2), an anchor assembly (86) having proximal (wound 89') and distal (88') anchors connected by a suture (89'), where the anchor assembly is adapted for adjustment of the length of suture between the anchors, and where the apparatus includes an anchor delivery system ("hollow needle or trocar"). Note: The introductory statement of intended use ("for securing a tissue fold within a patient") has been carefully considered but deemed not to impose any structural limitations on the claims patentably distinguishable over the device of Swanstrom et al., which is capable of being used as claimed if one desires to do so. Also, it has been held

that the recitation that an element is "adapted to" or "adapted for" (e.g., "adapted to form a tissue fold within a patient" and "adapted for adjustment of the length of suture") is not a positive limitation, but only requires the ability to so perform. It does not necessarily constitute a limitation in a patentable sense.

4. Claims 1, 8, and 17 are rejected under 35 U.S.C. 102(e) as being anticipated by Laufer et al. (6,494,888). Laufer et al. disclose, at least in figures 2-10, an apparatus for securing a tissue fold within a patient, where the apparatus includes an anchor assembly (730) having proximal (732) and distal (734) anchors connected by a suture (822), where the anchor assembly is adapted for adjustment of the length of suture disposed between the anchors while the anchor assembly is disposed across the tissue fold (by adjustment of the location of knot 823), and where the apparatus includes an anchor delivery system (700) and plication apparatus (740) adapted to form a tissue fold within a patient. Note: it has been held that the recitation that an element is "adapted to" or "adapted for" (e.g., "adapted for adjustment of the length of suture disposed between the proximal and distal anchors while the anchor assembly is disposed across the tissue fold") is not a positive limitation, but only requires the ability to so perform. It does not necessarily constitute a limitation in a patentable sense.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 9-12 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swanstrom et al (6,669,707) in view of Cope (6,699,263). Swanstrom et al. disclose the invention substantially as claimed. Swanstrom et al. disclose, at least in figures 5-7 and 11, an apparatus with an anchor delivery system including a needle (e.g. 17) and a pushrod (20), but do not disclose a flexible delivery tube that includes a proximal anchor. Cope teaches, at least in col. 4, line 17-60, a catheter (50) or flexible delivery tube for an anchor delivery system that includes a proximal anchor. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Cope, to include a flexible delivery tube that includes a proximal anchor in the apparatus of Swanstrom et al. Such a tube would allow delivery of anchors to internal tissues located deep within a patient's body or hollow organs.

7. Claims 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cope (6,699,263) in view of Harrison et al. (5,403,326). Cope discloses, at least in figures 6-8, a method for securing gastrointestinal tissue (11 and 13) substantially as claimed, where a length of suture (65) disposed between proximal and distal anchors (e.g., 30, 40) is adjusted to secure tissue, but Cope does not disclose that the tissue is

folded, and that a tissue fold is formed with a plication apparatus. Harrison teaches, at least in figures 5-8D, apparatuses and methods for securing a gastrointestinal tissue fold, including a plication apparatus (e.g., 40). It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Harrison et al., to apply the method of Cope to securing a gastrointestinal tissue fold, and to apply a plication apparatus to form the fold. The method of Cope would allow fundoplication of the stomach with an anchor assembly that can be adjusted according to the size of tissue to be folded; while a plication apparatus would allow manipulation of tissue to be secured with the anchor assembly.

Allowable Subject Matter

8. Claims 13 and 15 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

9. The following is a statement of reasons for the indication of allowable subject matter: None of the prior art of record, alone or in combination, discloses an apparatus including, inter alia, an anchor assembly with proximal and distal anchors and a length of suture between the anchors, an anchor delivery system including a flexible delivery tube, a needle, and an anchor tube coupled to a distal region of the flexible delivery tube; and an anchor pushrod adapted to reversibly trap the suture.

As allowable subject matter has been indicated, applicant's reply must either comply with all formal requirements or specifically traverse each requirement not complied with. See 37 CFR 1.111(b) and MPEP § 707.07(a).

Response to Amendment

10. Applicant's arguments with respect to claims 1-8 have been considered but are moot in view of the new ground(s) of rejection. Applicant's other arguments with respect to claims 1, 8-12, 14, and 18-20 have been fully considered but they are not persuasive: See the restated grounds of rejection above. That is, with respect to arguments regarding the Laufer reference: The anchor assembly is indeed adapted for or capable of adjustment of the length of suture disposed between the proximal and distal anchors "while the anchor assembly is disposed across the tissue fold." The anchor assembly includes a knotted suture, where the suture has been previously tied at a desired length, and where the suture can be unknotted or cut in order to retie the ends of the suture at another desired length.

With respect to arguments regarding the rejection based on the Swanstrom reference: Swanstrom indeed discloses a plication apparatus, i.e., an "endoscopic grasping tool," that is adapted to or is fully capable of grasping tissue and forming a tissue fold within a patient.

With respect to arguments regarding the rejection based on the references of Cope and Harrison et al.: The Examiner agrees with the Applicant that the Cope and Harrison patents disclose "different procedures intended for treatment of different indications," but disagrees with the Applicant in that "the apparatuses and methods taught by the Cope and Harrison patents are entirely incompatible." That is, both patents have, in common, apparatuses and methods directed to the joining of portions of gastrointestinal tissue; so it would have been obvious to one having ordinary skill in

the art to combine the teachings of the two patents. The "two hollow viscera" being anastomosed in the Cope reference are analogous to the two portions of gastroesophageal tissue being folded together and joined in the Harrison reference. Moreover, Cope indeed discloses a suture with a length that is adjustable according to thickness of tissue portions being joined. The Harrison reference was applied for the teaching of additional tools or plication apparatus used to manipulate gastrointestinal tissue portions to be joined.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (571) 272-4707. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor; Anh Tuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Julian W. Woo
Primary Examiner

April 18, 2007